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X. Summary of Safety and Effectiveness

The ArthroCare Arthroscopic Electrosurgery System™ is a high frequency electrosurgical device intended for use in arthroscopic surgery to resect soft tissue and provide hemostasis. The System is comprised of three components: the Multi-Electrode Wand, the Wand Cable, and the Controller. The System (K943450) was determined substantially equivalent on March 10, 1995.

The bipolar design of the ArthroCare Wand incorporates the return electrode into the shaft of the device. This means that a patient ground pad is not required as with monopolar electrodes. The energy flows back to the Controller via the integral return electrode rather than through the patient's body to the return pad. In addition, the ArthroCare Wand is designed to be operated in a physiological saline environment while the predicate products must be operated in a non-conductive environment, such as sterile water or glycine. This allows ArthroCare to achieve equivalent efficacy in tissue resection with less power requirements.

It is believed that the ArthroCare Multi-Electrode Electrosurgical System will be safe and effective when utilized for hip arthroscopy. There is considerable evidence in the literature as well as human and animal clinical data to support this determination. The ArthroCare System was cleared for use in the knee, shoulder, ankle and elbow by the U.S. Food and Drug Administration via Premarket Notification (K943450) in March of 1995. To date, the device has been used in over 5,000 arthroscopic procedures and physicians have reported that the System is effective in arthroscopic tissue ablation and hemostasis. There have been no reports of compromised patient safety in these procedures. We believe that the use of this device in the hip raises no new issues of safety or efficacy and will simply be an expansion of indications for use to another joint of the body.

The trend in surgery has been to reduce patient trauma, decrease recovery time and decrease health care costs by utilizing minimally invasive surgical techniques. The benefits of arthroscopic surgery are well documented. Compared to open surgical procedures, arthroscopy is a minimally invasive procedure that is significantly more cost effective. Arthroscopic procedures are usually shorter than standard open procedures, require less anesthetic, and the recovery period is shorter. One particular benefit of hip arthroscopy over conventional open surgery of the hip is that it obviates the need for dislocation of the hip to reach intra-articular pathology, thus avoiding the potential for

developing ischemia of the femoral head, which is a well known cause of femoral head necrosis.

Advances and refinement in instrumentation and methods of approach to the joint as well as development of potential indications have contributed to the establishment of arthroscopic procedures of the hip joint as a standard orthopedic tool. A review of the literature indicates that the procedure is a safe and effective method that will continue to occupy a niche in the orthopedic surgeon's armamentarium for treating hip disorders.

Human clinical data is available for this procedure. The following information was obtained from a clinical data base compiled by a physician with considerable experience performing this procedure. The data is derived from 199 hip arthroscopies performed on 177 patients.

This data represents a total of 199 hip arthroscopy procedures that were performed on 177 patients between March 1984 and February 1996. The data is taken from a physician's database that is a compilation of the patients that he has treated via hip arthroscopy. These patient's were selected to undergo hip arthroscopy after conservative methods (i.e. nonsteroidal anti-inflammatory medications, cortisone injections, physical therapy etc.) were exhausted. Though this data was not collected as part of a controlled study, the information provides a valuable illustration of the usefulness of this procedure.

The table below provides basic demographic data for all patients treated.

Procedure type	Mean age at time of procedure <i>(range 14 to 78)</i>	Female	Male
Hip arthroscopy	38	84	93

The table below provides an overview of outcomes of the procedures performed. Please note that this data represents a total of 177 patients that have undergone hip arthroscopy. Twenty-four of these patients received the procedure two or more times.

Procedure Type	Number of Procedures	Improved	Worse	No Change
Hip Arthroscopy	199	117 (59%)	5 (3%)	77 (39%)

At first glance, the percentage (59%) of patients that were improved after the procedure seems rather low. However, several factors must be taken into account when reviewing this data.

First, the average age of the patients who underwent this procedure is 38. For many of the younger, arthritic patients, the procedure was offered as a potential method of delaying the need for an open surgical procedure and total hip replacement. The average life span of a cemented total hip replacement is approximately 10 - 15 years and the life span of an un-cemented total hip replacement is approximately 15 - 20 years. Therefore, patients who receive total hip replacements very early in life may be faced with the surgery more than once because the hip will wear out and require replacement.

Second, many of these patients had chronic conditions of the hip including arthritis. The arthritic hip typically is less treatable by arthroscopy but the procedure is still considered to be warranted for the young patient as it offers the potential to delay total hip replacement.

In light of these factors, a 59% improvement rate is acceptable. Arthroscopy of the hip is being offered to younger patients as a potential alternative to the more risky, debilitating open procedure and total hip replacement.

In addition to the human clinical data, an in vivo, arthroscopic animal study was completed and submitted to provide clinical data to support the original 510(k) submission for this device (K943450), cleared March, 1995. The study compared the depth of tissue alteration of meniscal tissue in the intact joints of goats at both the recommended and maximum power settings for the treatment and control devices. The study demonstrated that the depth of tissue alteration and height and width of the ablation lesion were the same for the two devices at the manufacturer's recommended power settings. It was found that there is no significant difference in the safety and efficacy of the ArthroCare Multi-Electrode Arthroscopy System and a standard monopolar electrosurgery device. Please refer to Attachment A (K943450) pages 13 18 and Appendix B of Attachment B, for a comprehensive discussion of this study.

Ample evidence of the value of arthroscopy for the treatment of disorders of the hip can be found in the literature. Current arthroscopic text books include chapters on hip arthroscopy. The 1996 edition of the J.B. McGinty et al. text of Operative Arthroscopy contains three chapters on hip arthroscopy that discuss optimal approaches to the hip joint as well as indications and arthroscopic surgical treatment of the hip. Copies of these three chapters are provided in Appendix F.

In addition to arthroscopic texts, key scientific journals also contain a considerable number of articles discussing hip arthroscopy. Examples of journal articles describing hip arthroscopy are included in Appendix F. The literature discusses the currently defined indications for this procedure and the fact that proper patient selection is an important determinant of successful outcome. Some definitive indications for hip arthroscopy are undiagnosed hip pain, irrigation of infection, removal of foreign and loose bodies, synovectomy, debridement of osteoarthritis, and trimming and excision of labral tears.

Three arthroscopic surgical approaches to the hip have been described in the literature: anterior, posterior and lateral. The lateral approach is described as most favored due to the increased view of the joint as well as lowest associated risk of vascular or neural injury.

Review of the literature reveals that relatively few complications are associated with hip arthroscopy. The reported complications that may be associated with the procedure are; transient neuropraxia from traction, pressure wounds to the foot and perineum, sciatic and femoral nerve damage, and scuffing of joint surfaces.

With specific precautions, the complications associated with hip arthroscopy can be largely avoided. Careful observance of anatomic land marks will prevent damage to the sciatic nerve and femoral nerve and artery. Traction to distract the hip sufficiently will guard against scuffing of the cartilage surfaces and limiting the force and time of traction can serve to prevent nerve traction disorders.

Physicians are currently performing arthroscopic procedures in the hip joint and will continue to do so. The procedure has demonstrated utility for defined indications and can offer an attractive option to a patient faced with the prospect of a conventional open surgical procedure and in conjunction, the procedure offers the physician an additional valuable tool in hip surgery. As in other joints of the body, the ArthroCare Multi-Electrode Electrosurgery System will be safe and effective when used in arthroscopic procedures of the hip joint.